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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/623,801

07/22/2003

Peter Forsell

2333-122

5300

23117

7590

11/05/2010

NIXON & VANDERHYE, PC

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ARLINGTON, VA 22203

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

11/05/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/623,801	<b>Applicant(s)</b> FORSELL, PETER	
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,5-56,58-77 and 80-155 is/are pending in the application.
- 4a) Of the above claim(s) 5-16,20-55,61-77 and 80-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,17-19,56,58-60 and 83-155 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/04/2010</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/04/2010 has been entered.
2. Claims 1, 5-56, 58-77, and 80-155 are pending in this application. Claims 5-16, 20-55, 61-77, and 80-82 are withdrawn from consideration.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 8/04/2010 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 17-19, 56, 58-60, and 83-155 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Vincent** (U.S. Pat. No. **5,601,604**) in view of **Ishikawa et al.** (U.S. Patent No. **6,042,608**) and **Furst** (U.S. Pub. No. **20020099438**).

Claims 1, 17-19, 56, 58-60, and 83-155: Vincent discloses the claimed device, an implantable constriction device for forming a restricted stoma opening in the stomach of a patient, comprising an elongate composite structure or elongate means adapted to externally constrict the stomach of the patient, wherein said elongate composite structure comprises an elongate member **15**, a base material **16** surrounding or covering the elongate member, the base material making said structure self-supporting, an adjustment means **19** adapted to adjust the elongate member, or to mechanically adjust the non-inflatable composite structure to either enlarge or restrict the stoma opening (Figures 1-2), *except for* the device having property improving means for improving at least one physical property of said composite structure other than self-supporting properties, said property improving means including at least one layer applied on said base material intended to contact the stomach, and improving the anti-friction properties of said constricting means, as well as liquid impermeability, softness, strength, fatigue resistance, aggressive body fluid resistance, anti-friction properties, the

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layer being selected from a group consisting of a biocompatible metal layer or a viscoelastic material. Vincent also lacks the base material comprising a layer of silicone and a layer of polyurethane.

Ishikawa et al. teach a device meant to conform to a body with a base material comprising a layer of silicone and a layer of polyurethane (col. 8, lines 25-27; col. 14, lines 21-25). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the base material self-supporting structure with a layer of silicone and a layer of polyurethane, as taught by Ishikawa et al., to Vincent since it permits the device to exhibit optimum flexibility and elasticity close to the body.

Furst teaches property improving means comprising a coating or layer on a base material at least along a side of said elongate composite structure that is capable of contacting the stomach, said coating having better aggressive body fluid resistant properties than said base material, said coating being selected from the group consisting of a Teflon<sup>TM</sup> (polytetrafluoroethylene), Parylene<sup>TM</sup>, and a biocompatible metal coating selected from the group consisting of gold, silver, and titanium, and that biocompatible coatings are used to reduce inflammation, infection, irritation, and/or rejection of the device (page 5, paragraph 17). It would have been obvious to one of ordinary skill in the art to provide a coating on the elongate structure, as taught by Furst, to Vincent in order to reduce inflammation, infection, irritation, and/or rejection of the device.

Although Furst does not teach a property improving viscoelastic layer, Ishikawa et al. teach a silicone gel and it would have been obvious to one of ordinary skill in the

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art to provide an additional silicone gel layer surrounding the device of Vincent and Ishikawa that is made of a biocompatible material that further reduces the likelihood of injuring or damaging tissue during contact.

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1, 17-19, 56-58, 60, and 83-155 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/TODD E. MANAHAN/  
Supervisory Patent Examiner, Art Unit 3776